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105TH CONGRESS
2D SESSION

H. R. 3283

To amend title XVIII of the Social Security Act to provide for Medicare reimbursement of routine patient care costs for individuals participating in federally approved clinical trials and to require a report on costs of requiring coverage of these costs under group health plans and health insurance coverage.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 26, 1998

Mr. BENTSEN introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to provide for Medicare reimbursement of routine patient care costs for individuals participating in federally approved clinical trials and to require a report on costs of requiring coverage of these costs under group health plans and health insurance coverage.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicare Clinical Trial Coverage Act of 1998''.

SEC. 2. MEDICARE REIMBURSEMENT FOR INDIVIDUALS PARTICIPATING IN CLINICAL TRIALS.

(a) IN GENERAL.—Section 1862 of the Social Security Act (42 U.S.C. 1395y) is amended—

(1) in subsection (a)(1)—

(A) by striking ''and'' at the end of subparagraph (H);

(B) by striking the semicolon at the end of subparagraph (I) and inserting '', and''; and

(C) by adding at the end the following new subparagraph:

''(J) in the case of expenses incurred in connection with any phase of a Federally approved clinical trial (as defined in subsection (h)(1)), unless such expenses are for routine patient care costs (as defined in subsection (h)(2));''; and

(2) by inserting after subsection (g) the following new subsection:

''(h)(1) For purposes of subsection (a)(1)(J), the term 'Federally approved clinical trial' means a clinical trial which is approved by any of the following:

''(A) The Secretary.

''(B) The Director of the the National Institutes of Health.

''(C) The Commissioner of the Food and Drug Administration.

''(D) The Secretary of Veterans Affairs.

''(E) The Secretary of Defense.

''(F) The Secretary of Energy.

''(G) A nongovernmental research entity (as defined in the guidelines of the National Institutes of Health) or a peer-review and approved research program (as defined by the Secretary).

''(2)(A) Subject to subparagraph (B), for purposes of subsection (a)(1)(J), the term 'routine patient care costs' includes the costs associated with the provision of items and services that—

''(i) would otherwise be covered under this title if such items and services were not provided in connection with a Federally approved clinical trial; and

''(ii) are furnished according to the design of a Federally approved clinical trial.

''(B) Such term does not include the costs associated with the provision of—

''(i) an investigational drug or device, unless the Secretary has authorized the manufacturer of

such drug or device to charge for such drug or device; or

''(ii) any item or service supplied without charge by the sponsor of the Federally approved clinical trial.''.

(b) ASSURING COVERAGE UNDER MEDICARE+CHOICE PLANS.—Section 1852(d)(2) of such Act (42 U.S.C. 1395w–22(d)(2)) is amended—

(1) by striking ''and'' at the end of subparagraph (D);

(2) by striking the period at the end of subparagraph (E) and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(F) coverage is provided under the plan for routine patient care costs of Federally approved clinical trials (as such terms are defined in section 1862(h)).''.

(c) EFFECTIVE DATE.—The amendments made by this section apply to items and services furnished on or after January 1, 1999.

SEC. 3. REPORT ON COSTS OF COVERAGE OF BENEFITS FOR FEDERALLY APPROVED CLINICAL TRIALS UNDER GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE.

The Secretaries of Health and Human Services and Labor shall jointly prepare and submit to Congress a report on the costs associated with requiring that group health plans and health insurance coverage do not deny payment of routine patient care costs for services furnished in connection with Federally approved clinical trials (as those terms are defined in section 1862(h) of the Social Security Act).

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